

K963422

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510(k) SUMMARY**1. PERSONNEL AND DATE (807.92(a)(1))****1.1. Submitter**

Kenad SG Medical Inc.
2692 Huntley
Memphis, TN 38132

1.2.. Contact Person

Kenneth Elmore
President and CEO
Kenad SG Medical Inc.

1.3.. Date Of summary Preparation

This summary was prepared in July thru August 1996.

2. DEVICE NAME (807.92(a)(2))

As noted in the Cover Letter, six similar devices are grouped within this 510(k) notification. These devices differ only in minor design aspects. Their function, application and use is identical.

2.1. Trade Or Proprietary Name

Protective Mitt is the trade or proprietary name for the devices which are the subject of this Premarket Notification Submission. Within this name, there are four Kenad Protective Mitts.

KENAD Catalog #	Description	KENAD Catalog #	Description
50-1000	Adult w/o stays	50-1100	Adult w/ stays
50-1010	Child w/o stays	50-1110	Child w/ stays
50-1020	Infant w/o stays	50-1120	Infant w/ stays

2.2. Common Or Usual Name

Protective Restraint 21CFR 880.6760

3. LEGALLY MARKETING DEVICE (807.92(a)(3))

The Kenad Protective Mitts subject to this Premarket Notification Submission are comparable to Protective Mitts from Danek Medical, Inc. Danek filed a premarket notification for Protective Mitts November 23, 1982

4. DEVICE DESCRIPTION (807.92(a)(4))

4.1. General Description

The Kenad Protective Mitts subject to this Premarket Notification are devices that comprise the following modules, cited in this document

Mitt- Two sided flexible material. The inside, which faces the hand, is polyurethane, and the outside is polyester foam.

Mesh Port Covering- Nylon mesh.

Wrist Strap and Buckle- Flexible polypropylene and polished nickel plated buckle.

Stay- Inflexible aluminum strip.

4.2. How Protective Mitts Function

The hand is placed into the mitt which is comfortably fitted at the wrist with a Velcro closure. The wrist is then snugly surrounded by the Wrist Strap and Buckle.

If needed, the Wrist Strap can be joined via a Quick release Buckle to an Anchor Strap to limit limb movement.

Stays placed in some mitts limit mitt flexibility to limit hand motion within the mitt.

5. INTENDED USE (807.92(a)(5))**5.1. Indications**

Kenad Protective Mitts are indicated for medical purposes where hand and finger movement must be limited to prevent grasping tubes or picking or scratching dressings and wounds.

5.2. Patient Population

Kenad Protective Mitts are used with adults and children.

5.3. Indications Different From Substantially Equivalent Device

Indications and patient populations for the Kenad devices are identical to the legally marketed device cited in this document

6. COMPARISON TO LEGALLY MARKETING DEVICE (807.92(a)(6))

Kenad Protective Mitts are comparable to Protective Mitts from Danek Medical, Inc. A comparison of these devices are provided in this Premarket Notification Submission.

7. PERFORMANCE DATA (807.92(b))

More than 5000 pairs of Kenad Protective Mitts were sold over the last 5 years. Assuming 100% usage, there have been more than 10,000 patient hand contacts over the last 5 years. During this time, Kenad received no patient injury or product failure complaints about the Protective Mitts.

8. SAFETY, EFFICACY AND PERFORMANCE CONCLUSION (807.92(b)(3))

The absence of patient injury or product failure complaints following more than 10,000 product uses over 5 years indicates these products are safe and effective.